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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,427	07/03/2001	Jon Elliot Adler	P 0282558 2001-028A	8334

909 7590 12/23/2002
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/23/2002

14/

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/897,427

Applicant(s)

ADLER ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 12-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

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DETAILED ACTION

1. Formal Matters

A. Claims 1-99 are pending in this application and were subject to restriction in Paper No. 11 dated 9/19/02. In Paper No. 13, filed 11/19/02, Applicants elected Group I, claims 1-11, with traverse. Applicants argue that a search for Group I would necessarily overlap a search with the non-elected Groups and, therefore, that claims directed to T1R DNAs and polypeptides should be rejoined. These arguments have been considered, but are not deemed persuasive. A search for Group I would not overlap a search for Groups drawn to specific polypeptides or polynucleotides. Elected claims 1-11, unlike the non-elected Groups, do not recite specific SEQ ID NOs. Therefore a search of Group I would not necessarily overlap with a search of any of the other Groups. Group I is drawn to methods of using proteins, whereas the remaining Groups are drawn to isolated polypeptides and polynucleotides. Therefore, the restriction is deemed proper and is, therefore, made FINAL.

2. Oath/Declaration

A. The Oath is objected to since it recites that the present application claims priority from provisional application no. 60/880,606, which does not exist in the Office's records.

3. Title

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title recites T1R hetero-oligomeric taste receptors. However, the claims are drawn toward method of screening compounds that modulate taste signaling.

4. Specification

A. The specification is objected to since the first line of the specification refers to US Provisional Application 60/280,606. However, this application is not the parent application to the present invention. This is why Applicants' records are inconsistent with those of the Office. As recited on the Bibliographic Data Sheet, the filing date of the supposed parent case, 60/280,606, is correct. It is the claim to the provisional which is incorrect.

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- B. The specification is objected to since page 69 of the specification is objected to since the word "herein" on line 12 is underlined. Furthermore, the "Gα15" on lines 7, 19, 21 and 22 is written as a square instead of an "a."
- C. The specification is objected to since page 10, line 7 refers to a US Application. If this application has issued as a US Patent, the Patent No. should be used.
- D. The syntax of claim 1 can be improved by adding the word "as" between the words "act" and "a."
- E. The syntax of claim 2 can be improved by rewording the phrase "is measured by assayed."

5. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- A. The Examiner brings to Applicants' attention that claims 1-11 may be provisionally rejected under the judicially created doctrine of double patenting over one or more claims of copending Application No. 10/179,373, 10/191,058 and 10/035,045. Upon performing a search of the present invention, Applications 10/179,373, 10/191,058 and 10/035,045 were identified as having one or more inventor in commons. However, Application 10/025,150 was not available to the Examiner at the time this Office Action was written. Applicants are hereby informed that a provisional double patenting rejection may be made in a subsequent Office Action.

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6. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 3, 4, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for compounds that modulate sweet taste signaling by using a promiscuous G protein, does not reasonably provide enablement for a method of screening for compounds that modulate taste signaling by using nucleic acid constructs other than a promiscuous G protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, regarding claim 3, the breadth of the claims is excessive with regard to Applicants claiming the screening method wherein the cell is transfected with at least one additional nucleic acid construct encoding a gene involved in taste signaling. Applicants have only provided guidance and working examples of transfecting a promiscuous G protein into the test system. No other guidance or working examples of any other constructs is disclosed in the specification. Furthermore, it is not predictable to one of ordinary skill in the art what other constructs involved in taste signaling could be transfected into the test system.

Therefore, due to the excessive breadth of the claims regarding the use of any nucleic acid construct encoding a gene involved in taste signaling other than a promiscuous G protein along with the lack of guidance and working examples of these constructs as well as the lack of predictability as to what other constructs can be transfected into a cell in order to modulate taste signaling, the Examiner holds that undue experimentation is necessary to practice the claimed invention.

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7. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-11 are confusing since the metes and bounds of "activity" in claims 1 and 6 is not known. It appears from the specification that the activity to be measured is an intracellular signaling activity. Therefore, it is suggested that the claims be amended to recite "measuring an intracellular signaling activity." Claims 2-5 and 7-11 are also rejected since they depend from rejected base claims.

B. Claims 1-11 are confusing since claims 1 and 6 recite measuring the activity of the receptors wherein the receptors act as heterooligomers. It appears that the activity to be measured is the formation of this heterooligomeric complex. The clarity of the claim can be improved by amending part (i) of the claims to recite, for example, "...a cell co-expressing at least two T1R receptors or polypeptides as a hetero-oligomeric complex..." Furthermore, in claim 1, there is no recitation of an end step saying, for example, "wherein an increase or decrease in said activity means that a compound is a modulator..."

C. Claim 6 is confusing since it is not clear if the two receptors in part (ii) are the same as in part (i). It is suggested, for example, that part (ii) be amended to recite "second cell co-expressing said "at least two T1R receptors..." Claims 7-11 are also rejected since they depend from claim 6.

D. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the limitation "modulatory compounds" into claim 6. There is insufficient antecedent basis for this limitation in the claim. Furthermore, claim 7 recites that the modulatory compounds are selected from the group consisting of "activators, inhibitors, stimulators, enhancers, agonists and antagonists." First, it is not clear what receptors these activators, inhibitors, stimulators, enhancers, agonists and antagonists are involved with. In other words, activators of what? Secondly, if these compounds were already known to have activity at the taste receptor, then it is not understood why these compounds are being screened.

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8. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuker et al. (US Patent No. 6,383,778) in view of Montmayeur et al. (Nat. Neurosci. 4(5):492-498, 2001). The claims recite a method of screening for compounds that modulate taste signaling by contacting cells co-expressing at least two T1R receptors and measuring the activity by one of various means. Zuker et al. teach methods for screening for compounds that modulate signaling by expressing DNA encoding taste receptors into cells and measuring activity of candidate compounds (column 29, line 17 – column 36, line 7). Zuker et al. also teach that promiscuous G proteins can also be used to measure taste receptor activity (column 9, lines 26-30). Zuker et al. do not teach cells co-expressing two or more taste receptors.

However, Montmayeur et al. do teach T1R receptors and that most T1R3 expressing cells also express a gene encoding a related receptor, T1R2. Montmayeur et al. also teach that these two receptors may function as heterodimers (Abstract; Introduction; last paragraph of left column on page 496). Therefore, given the suggestion of Montmayeur et al. that cells express at least two T1R receptors and that these receptors are likely expressed as heterodimers, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have expressed more than one T1R taste receptor into the cells of Zuker et al. in order to screen for compounds which modulate these two receptors, especially given the suggestion by Montmayeur et al. that the formation of T1R heterodimers could explain how sucrose and saccharin can stimulate different signal transduction cascades in a single taste cell (page 496, left column, last full paragraph).

9. Conclusion

A. No claim is allowable.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 20, 2002

A handwritten signature in black ink, appearing to read "R. Landsman", is positioned below the typed name and title.